SHRI GURU RAM RAI UNIVERSITY

Patel Nagar, Dehradun-248001, Uttarakhand, India

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Syllabus

Pre-Ph.D. Course Work (Pharmaceutical Sciences)

Effective from Academic Session
(2023-2024)

Course Structure and the Assessment Scheme of Pre Ph.D. Course Work Syllabus

S.N.	Paper Code	Subject	Credits L:T:P	Total credit	Total marks (External + Internal)	Minimum marks to be scored for successful completion
1.	**PRMC 101**	Research Methodology	2:1:1	4	80 (60+20)	40
2.	**RPEC 102**	Research & Publications Ethics	1:1:0	2	40 (30+10)	20
3.	**PPSC 103A or PPSC 103B (only for Pharmacy Practice)**	Subject Specific (core paper): A. Advanced Analytical Techniques or B. Clinical & Hospital Pharmacy	2:1:1	4	80 (60+20)	40
4.	**PPSE 104 (A/B/C/D/E)**	Subject Specific (elective paper) A. Pharmaceutical Chemistry B. Pharmaceutical Formulation Development C. Pharmacological Screening Methods D. Advanced Pharmacognosy E. Fundamentals of Clinical Research	2:1:1	4	80 (60+20)	40
5.	**PCRF 105**	Field work	0:2:2	4	80 (00+80)	40
Total				**18**	**360**	**180**

Programme Outcome:

1. Deeper understanding to have deeper understanding of different imaging modalities for their application in various clinical conditions of patients.
2. Research and development To prepare students for research and development in respective areas
3. Problem solution Problem solving by applying reasoning and technical inputs
4. To study and understand the impact of quality assurance and quality control techniques for proper maintenance of imaging modalities.
5. Lifelong learning Recognize the need for, and have the preparation and ability to engage in independent

and life-long learning in the broadest context of technological change.

6. Leadership and self-reliance Impact leadership abilities to the students to lead and excel in their respective fields. Also, the training will make students self-reliant.

Programme Specific Outcomes:

Upon successful completion of the Ph.D. Radiation Physics and Imaging Technology course, the students will be able to:

1. Keep pace with the expanding frontiers of knowledge and provides research training relevant to the present advancements in medical imaging technology.
2. Use the scientific methods, and critical thinking skills to ask questions and solve problems.
3. Write a good research report and acquires the skill of presenting data in graphical form.
4. Follow a protocol independently, including interventional technique and equipment, practicing advanced procedures and accurately performing all radiological imaging procedures.
5. Analyze experimental results, differentiating between expected and unexpected results, trouble shooting, interpreting results and making conclusions.
6. Demonstrate proficiency in maintaining a safe work place, including observation of departmental safety procedures with the help of quality check, use of personal protective equipment, identification of radiation hazards.
7. Demonstrate improvement in communication skills, including maintenance of case reports, oral presentations and written reports.
8. Identify carriers in radiation physics and imaging technology and skills required for landing a job.
9. Work in a government-based entity such as Universities, research institutes or at private centers as research scientists/assistant in the native country and outside as well

Paper-I: Research Methodology (Compulsory),
Code: PRMC-101

Credit: 04

Course Outcome:

1. To develop understanding of the basic framework of research process.
2. To develop an understanding of various research designs and techniques.
3. To identify various sources of information for literature review and data collection.
4. To develop an understanding of the ethical dimensions of conducting applied research
5. Appreciate the components of scholarly writing and evaluate its quality.
6. Create the research design and experimental approaches to conduct research.

Unit I-Concept & Types of Research **01**

Meaning and importance of Research, Types of Research, Selection and formulation of Research Problem, Research Design, Classification of Research, Pure and Applied Research, Exploring or Formulative Research, Descriptive Research, Diagnostic Research/Study, Evaluation research/Studies, Action Research, Experimental Research, Historical Research.

Unit II –Methods Research **01**

General Survey of various Methods including Survey Method, Interdisciplinary Method, Case Study Method, Sampling Method, Observation Method, Interview Method, Schedule Method, Questionnaire Method, Documentary Method, Library Method, Historical Method and Scientific Method. Characteristic Features of Scientific Method; Empirical Verifiable, Cumulative, Self - Correcting, Deterministic, Ethical & Ideological neutrality (Value Free).

Unit III - Data Collection and Data Analysis **01**

Collection, Objectives and Classification of Data, Aims, Methods and Objects of Tabulation of Data, Forms and Processes of Interpretation and Presentation of Data, Primary, Secondary and Tertiary Data, Construction and adaptation of instruments, administration of questions and tests, Data organization in SPSS & Excel, Graphical representation of data, Testing of Hypothesis: Logical and Statistical Techniques.

Unit IV: Report Writing **01**

Locating Information on a Topic of Interest, Acquiring Copies of Articles of Interest, The Nature of Scientific Variables, Conceptual Versus Operational Definitions of Variables, Levels of Measurement, Various Paradigms, The Basic Format for a Research Report, Identification of the Parts of a Research Report, Citation and Referencing Styles, Essentials of Report Writing, Aids for Writing Good Research Report.

References:

1) Bagchi, Kanak Kanti (2007) Research Methodology in Social Sciences: A Practical Guide, Delhi, Abijeet Publications.

2) Kothari, C.R (2004) Research Methodology: An Introduction, Delhi, New Age.

3) Cooper, R. Donald and Pamela S. Schindler (2003) Business Research Methods, Delhi, Tata McGraw-Hill.

4) Flyvbjerg, Bent (2001) Making Social Science Matter: Why Social Inquiry Fails and How it can Succeed Again, United Kingdom, Cambridge University Press.

5) Goodde and Hatte (1952) Methods in Social Research, New York, McGraw – Hill.

Paper-II: Research & Publication Ethics (Compulsory), **Code:** RPEC-102

Credit: 02

Course Outcome:

1. To develop an understanding of research ethics, publications misconduct and plagiarism.
2. To develop Intellectual honesty and research integrity.
3. To identify various sources of information for data bases and research matrices.
4. To develop an understanding of Open access publications and initiatives.
5. Appreciate the components of scholarly writing and evaluate its quality.
6. Create the research matrices based on cite score.

Unit I-Philosophy and Ethics **0.2**

Introduction to philosophy: definition, nature and scope, concept, branches. Ethics: definition moral philosophy, nature of moral judgements and reactions.

Unit II-Scientific Conduct **0.3**

Ethics with respect to science and research, Intellectual honesty and research integrity, Scientific misconducts: Falsification and Plagiarism (FFP), Redundant publication: duplicate and overlapping publication, salami slicing, Selective reporting and misrepresentation of data.

Unit III-Publication Ethics **0.5**

Publication ethics: definition, introduction and importance, Best practices / standards setting initiatives and guidelines: COPE, WAME, etc. Conflicts of interest, Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types, violation of publication ethics, authorship and contributor ship, Identification of publication misconduct, complaints and appeals, Predatory publishers and journals Practice.

Unit IV-Open Access Publishing **0.25**

Open access publications and initiatives, SHERPA / RoMEO online resource to check publisher copyright and self-archiving policies, Software tools to identify predatory publications developed by SPPU, Journal finder / journal suggestion tools viz. JANE, Elsevier journal Finder, Springer, Journal Suggester, etc.

Unit V-Publication Misconduct **0.25**

Group Discussion, Subject specific ethical issues, FFP, authorship, Conflicts of interest, Complaints and appeals: examples and fraud from India and abroad. Software tools, Use of plagiarism software like Turnitin, Urkund and other open source software tools.

Unit VI-Databases and Research Metrics **0.5**

Databases, Indexing databases, Citation databases: Web of Science, scopus, etc., Research Metrics, Impact factor of journal as per journal Citation report, SNP, SJR, IPP, Cite score, Metrics: h-index, g index, i10 index, altmetrics.

Paper III: Advanced Analytical Techniques (Core paper)

Code: PPSC-103A

Credit-04

Course Outcome:

1. The objective of this course is to understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
2. The students will be able to classify the chromatographic separation and analysis of drugs.
3. The students will be able to develop in depth knowledge about modern pharmaceutical analytical techniques.
4. The students will be able to list the qualitative analysis of drugs using various analytical instruments.
5. The students will be able to determine pharmaceutical instrumental techniques used in drug analysis.
6. The students will be able to elaborate knowledge about modern pharmaceutical analytical techniques.

Unit I – Spectroscopy:

a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Woodword's Fieser, Fieser Kuhn and Nelson rule, Spectral correlation with structures of compounds and Applications of UV-Visible spectroscopy.
b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies, Interpretation of spectra's of compounds and Applications of IR spectroscopy.
c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quencher Instrumentation and Applications of fluorescence spectrophotometer.
d) NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, coupling constant, Nuclear magnetic double resonance, Brief outline of principle of FT-NMR, Interpretation of spectra's of compounds to the structure elucidation.
e) Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks, Applications of mass spectroscopy to structural elucidation of compounds. GC-MS and LC-MS Principle and Application.

Unit II - Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a. Paper chromatography b. Thin Layer chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. HPTLC h. Electrophoresis.

Unit III - Immunological assays:

RIA (Radio immuno assay), ELISA, Bioluminescence assays.

References:

1. Spectrometric Identification of Organic compounds-Robert M Silverstein, Sixth ed., John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry-Beckett and Stenlake, Vol II, 4th ed., CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

Paper III: Clinical & Hospital Pharmacy (Core paper)

Code: PPSC-103B

Credit-04

Course Outcome:

1. Fundamental knowledge about hospitals, hospital pharmacy & its services.
2. Explain the services provided by clinical pharmacists in healthcare settings.
3. Apply the basic concept of pharmaceutical care for providing clinical services in healthcare settings.
4. Examine various functions of health care professionals towards clinical services.
5. Improving skills in optimizing various hospital pharmacy services to improve pharmaceutical care.
6. Create continuing professional development programs & practices of hospital pharmacist.

Unit I Introduction to Clinical Pharmacy
Definitions, development and scope of clinical pharmacy.

Unit II Introduction to daily activities of a clinical pharmacist
a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) b. Ward round participation c. Adverse drug reaction management d. Drug information and poisons information e. Medication history f. Patient counselling g. Drug utilization evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy services

Unit III Patient data analysis
The patient's case history, its structure and use in evaluation of drug therapy & understanding common medical abbreviations and terminologies used in clinical practices.

Unit IV Drug &Poison information
a. Introduction to drug information resources available
b. Systematic approach in answering DI queries
c. Critical evaluation of drug information and literature
d. Preparation of written and verbal reports
e. Establishing a Drug Information Centre

Unit V Pharmacovigilance
a. Scope, definition and aims of pharmacovigilance.
b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment
c. Reporting, evaluation, monitoring, preventing & management of ADRs
d. Role of pharmacist in management of ADR.

Unit VI Patient counselling Techniques
Communication skills, including patient counseling techniques, medication history interview, presentation of cases.

Unit VII Hospital pharmacy - Organization and management
a. Organizational structure - Staff, Infrastructure & workload statistics
b. Management of materials and finance
c. Roles& responsibilities of hospital pharmacist

Unit VIII Hospital drug policy
a. Pharmacy and Therapeutic committee (PTC)
b. Hospital formulary
c. Hospital committees – Infection committee – Research and ethical committee

Unit IX Hospital pharmacy services
a) Procurement & warehousing of drugs and pharmaceuticals
b) Inventory control Definition, various methods of Inventory Control- ABC, VED, EOQ, Leadtime, safety stock
c) Drug distribution in the hospital
   i) Individual prescription method
   ii) Floor stock method
   iii) Unit dose drug distribution method

References-

1. Practice Standards and Definitions- The Society of Hospital Pharmacists of Australia.
2. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarathi etal, Orient Orient Langram Pvt. Ltd. -ISSBN8125026.
3. Hospital pharmacy by William .E. Hassan
4. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S.Qadry. Revised by R. K.Goyal & R.K .Parikh.

Paper IV: Pharmaceutical Chemistry (Elective)
Code: PPSE 104A

Credit-04

Course Outcome:

1. Outline the chemistry of drugs & pharmaceuticals.
2. Understand the chemistry of drugs with respect to their pharmacological activity.
3. Utilize the quality control aspects of chemical substances used in pharmaceuticals.
4. Analyze the pharmacological uses, storage and stability issues of such chemical substances used as drugs.
5. Explain the quantitative and qualitative analysis, impurity testing of the chemical substances given in the official monographs.
6. Discuss different types of formulations / dosage form available and their brand names.

Unit I Photochemical Reactions:
Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photofragmentation. Pericyclic reactions: Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

Unit II Catalysis:
Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. Homogenous catalysis, hydrogenation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler- Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs. Transition-metal and Organo-catalysis in organic synthesis Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. Phase transfer catalysis - theory and applications.

Unit III Stereochemistry & Asymmetric Synthesis:
Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis.

Unit IV Chemistry of peptides:
Coupling reactions in peptide synthesis, Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond 10 formation, deprotection and cleavage from resin, site-specific chemical modifications of peptides Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.

Unit V Interpretation of spectra
Interpretation of spectra from UV, IR, PMR, CMR, 2DNMR and Mass spectrophotometer for structure elucidation of organic compounds.

References:

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.

4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.
7. Principles of organic synthesis, ROC Norman and JMCoxan, Nelson thorns
8. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991. 9. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

Paper IV: Pharmaceutical Formulation Development (Elective)
Code: PPSE 104B

Credit-04

Course Outcome:

1. Remember the various approaches for development of novel drug delivery systems.
2. Understand the criteria for selection of drugs and polymers for the development of NTDS
3. Apply the knowledge gained in making Targeted Drug delivery systems, Micro-capsules, Niosomes, Aquasomes, Phytosomes, Electrosomes, Pulmonary drug delivery.
4. Examine Targeted drug delivery, Microsomes, Pulmonary drug delivery etc.
5. Evaluate the developed targeted drug delivery systems
6. Develop, Formulate Nucleic acid based, therapeutic, Targeted drug delivery system.

Unit I Preformulation Studies:
Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

Unit II Formulation Additives:
Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments factorial design for product and process development.

Unit III Solubility:
Importance, experimental determination, phase solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods co-solvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

Unit IV Dissolution:
Theories, mechanisms of dissolution, in-vitro dissolution testing models - sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus - designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Bio relevant media, in-vitro and in-vivo correlations, levels of correlations.

Unit V Product Stability:
Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API &tablets). Solid state stability and shelf-life assignment. Stability protocols, reports and ICH guidelines.

References:
1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thed, B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4 Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rded., CBS publications, New Delhi, 2008.

8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rded., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Inc, New York, 2005.
11. W. Grimm - Stability testing of drug product Marcel Dekker
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II.,4th ed., 2004. CBS Publishers & distributors, New Delhi,
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physico chemical properties of Drug substances, Ellis Horwood Ltd. England, 1988

Paper IV: Pharmacological Screening Methods (Elective)
Code: PPSE 104C

Credit-04

Course Outcome:

1. Understand the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and Organisation for Economic Co-operation and Development (OECD) guidelines.
2. Study of various screening methods used in preclinical research.
3. Illustrate the techniques for blood collection in laboratory animals.
4. Analyze and interpret experimental data.
5. Plan for selection of research topic.
6. Design of grouping of animals in preclinical research.

Unit 1

Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

Unit 2

Dose selection in Animal Experimentation, calculation and conversions, preparation of drug solution/ suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

Unit 3

Preclinical screening models for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics

Unit 4

Preclinical screening models for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti-aggregatory, coagulants, and anticoagulants.
Preclinical screening models for antiulcer, antidiabetic, anticancer and antiasthmatics.

Unit 5

Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics,
Preclinical screening models for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

References:

1. Fundamentals of Experimental Pharmacology 7th/2019 Author: M. N. Ghosh, ISBN: 9788190296507, Publisher: Hilton & Company, Edition: 7th.
2. Kulkarni, S. K. Handbook of experimental pharmacology 3rd edition vallabh publication New Delhi.
3. CPCSEA guidelines for laboratory animal facility.
4. Drug Discovery and Evaluation: Pharmacological Assays, 2007 by Hans Vogel Publisher: Springer; 3rd completely rev., updated and enlarged ed. edition (November 20, 2007) Language: English, ISBN-10: 3540714200.
5. Drug Screening Methods by S. K. Gupta Publisher: Jaypee Brothers Medical Publishers (P) Ltd. (December 1, 2004), Language: English, ISBN-10: 8180613976, ISBN-13: 978-8180613975.

Paper IV: Advanced Pharmacognosy (Elective)
Code: PPSE 104D

Credit-04

Course Outcome:

1. Understand the Advanced basic description and knowledge about Plant drug cultivation, Nutraceuticals, Phytopharmaceuticals and Pharmacovigilance of natural origin drugs.
2. Elaborative study and explanation regarding Advanced Pharmacognosy i.e. Phyto pharmaceuticals and Nutraceuticals, Marine Natural products.
3. Detailed discussion regarding Phyto pharmaceuticals, GAP and GACP guidelines.
4. Explanation of Application part of Cultivation, Nutraceuticals and Phytopharmaceuticals.
5. Learn utilization and importance of advanced pharmacognosy concepts.
6. Understand Role of Phyto pharmaceuticals for Herbal drug Research.

Unit I Plant drug cultivation

General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants - Ex-situ and In-situ conservation of medicinal plants.

Unit II Marine natural products

General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

Unit III Nutraceuticals

Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following - i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

Unit IV Phytopharmaceuticals

Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β-Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limoneneii) α– Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids – Ellagic acid
f) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
i) Miscellaneous
j) Analytical Profiles of: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.

Unit V Ethnobotany and Ethnopharmacology

Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, new development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

References:

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modern Methods of Plant Analysis-Peach & M.V. Tracey, Vol. I &II
4. Textbook of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol. I to IV.
6. Natural products: A lab guide by Raphael Ikan, Academic Press 1991.
7. Glimpses of Indian Ethanopharmacology, P. Pushpanga dam. Ulf Nyman. V. George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products-Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York,1998
15. Recent Advances in Phytochemistry-Vol.1&4: Scikel Runeckles-Appleton Century crofts.
16. Text book of Pharmacognosy, C.K. Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutosh kar, New Age Publications, New Delhi

Paper IV: Fundamentals of Clinical Research (Elective)
Code: PPSE 104E

Credit-04

Course Outcome:
1. Understanding of New drug Discovery & Drug development process and various terminology used in Clinical Research.
2. Fundamental knowledge of designing, conducting, and documenting the clinical trial process and their rationale.
3. Developing skills of clinical trial process viz clinical trial execution & monitoring, procurement & storage of investigational product, clinical trial data management etc.
4. Basic knowledge of essential clinical trial documents and roles & responsibilities of the clinical trial study team.
5. Appraise the various ethical & regulatory principles to be followed during Clinical trials.
6. Apply knowledge of Quality assurance & Quality control in clinical trials for regulatory compliance.

Unit -1 Drug development process:

Introduction, Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

Unit II Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice –ICH, GCP, Central drug standard control organization (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB/IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICHGCP
    a. Sponsor
    b. Investigators
    c. Clinical research associate
    d. Auditors
    e. Contract research coordinators
    f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent n Process
13. Data management and its components
14. Safety monitoring in clinical trials

References:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

Paper V: Field Work

Code: PRDF-105

Credit-04

Assessment will be based on work assigned by head of the department like to attend or present research paper/s in Seminar/ conference, write up on review literature and field visits for sample collection/tour report submission etc.